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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,952	03/30/2001	Charles David Claude	1225.003US1	6598

7590 05/14/2003

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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/14/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/822,952

Applicant(s)

CLAUDE, CHARLES DAVID

Examiner

Konata M. George

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1616

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

## Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on RCE filed February 10, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16, 17 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16, 17 and 44-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 1-13, 16, 17 and 44-47 are pending in this application.

#### ***Request for Continued Examination (RCE)***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 10, 2003 has been entered.

#### ***Action Summary***

2. The rejection of claims 1-17 and 44-47 under 35 U.S.C. 112, first paragraph is being maintained for the reasons stated in the office action dated August 9, 2002.
3. The rejection of claims 1, 2, 4, 5, 10, 11 and 17 under 35 U.S.C. 102(b) as being anticipated by Eury et al. is being maintained for the reasons stated in the office action dated August 9, 2002.
4. The rejection of claims 1-13, 16 and 17 under 35 U.S.C. 102(e) as being anticipated by Hossainy et al. is being maintained for the reasons stated in the office action dated August 9, 2002

Fig. 1  
11 → drug enriched polymer  
12 → bulk polymer

#### ***Response to Arguments***

5. Applicant's arguments filed November 26, 2002 have been fully considered but they are not persuasive.

Applicant argues that the limitation of "the preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymer phase is substantially or completely devoid of the drug" is supported in the specification. It is the examiners position that page 4, lines 24-30 of the specification teaches that the drug is added to a polymer blend. Nowhere is it shown that the bulk polymer phase will be substantially or completely devoid of the drug. Applicants also assert that Eury and Hossainy do not contain the limitations, namely a bulk polymer phase; drug incorporated into the drug-enriched phase. However, Eury clearly teaches a polymeric material and a drug and porsigen material that can be contained within the polymeric material. It is the understanding of the examiner that the polymeric material can be considered a bulk polymer, and that drug and posigen material can be considered a drug-enriched phase. Hossainy teaches a film-forming polymer used over a stent, with a top coating placed over the polymer. The film-forming polymer can be used to deliver therapeutic and pharmaceutical agents, and the top coating can be used to delay release a pharmaceutical agent. It is the view of the examiner that the topcoat can be considered a bulk polymer, and the film-forming polymer a drug-enriched phase. With respect to claims 44-47, it is not evident where a drug release system for a stent containing a first polymer and a second polymer being significantly or completely insoluble in the first polymer is taught in the instant application. As shown by Eury et al., the polymeric material can be poly (ethylene-co-vinyl acetate). Eury also teaches that a drug and porsigen material can be contained within the polymeric material.

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***Conclusion***

6. Claims 1-13, 16, 17 and 44-47 stand rejected.


***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
1616